



moor instruments

laser Doppler blood flow assessment

K063586

7 510(k) Summary

Submitter: Moor Instruments Ltd

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Contact: Xiabing Huang

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Date: November 27, 2006

Model Name: moorFLPI Full-Field Laser Perfusion Imager

Model Number: moorFLPI

Common Name: Full-Field Laser Perfusion Imager

Classification Name: Extravascular blood flow probe, DPT, 21 CFR 870.2120
Laser surgical instrument for use in general and plastic surgery and in dermatology, GEX, 21 CFR 878.4810

Regulatory Status: Class II

Establishment Reg No: 8043564

Type of 510(k): Traditional

Reason for submission: New device

Predicate Device: moorLDI2-IR Infrared Laser Doppler Imager
510(k) Number K032841

JAN 25 2007



7.1 Description of the Device

The moorFLPI is a device to perform non-contact imaging of tissue blood perfusion in the microcirculation, for example skin, using speckle contrast analysis. The tissue surface is illuminated with a diverging infra-red laser beam resulting in a laser speckle pattern. The pattern is imaged by a CCD camera and image processing of the speckle contrast is used to generate colour code images of the tissue blood perfusion in the microcirculation.

7.2 Intended Use

The moorFLPI Full-Field Laser Perfusion Imager is intended for blood flow measurements in the microcirculation. This device is intended for clinical research use.

7.3 Technological Characteristics

Tissue is illuminated by floodlighting with a diverging infra-red laser beam. The tissue is imaged with a CCD camera and video data is acquired by a PC. Image processing software on the PC is used to generate colour-coded maps of tissue perfusion. The image processing software uses the fact that high perfusion produces rapid variation in the laser speckle pattern, which is integrated by the CCD to produce an area of low contrast (seen as blurring of the speckle pattern in the video image). Conversely, low perfusion causes little variation in the speckle pattern and as a result a high contrast area of well-defined speckle is produced in the video image. Contrast is quantified and the resulting flux is colour-coded to produce a perfusion image.

The moorFLPI uses a large diameter diverging laser beam to illuminate an area of tissue and measures tissue perfusion at all points in the image simultaneously, hence the “Full-Field” designation in the device name. The predicate device uses a collimated laser beam to sequentially illuminate very small areas of tissue and generates images by scanning the beam in a raster pattern. These differences in the means to capture a single frame image mean that the moorFLPI is able to generate images more rapidly than the predicate device. The moorFLPI records images at video rates (25 frames/second) and the moorLDI2-IR takes approximately 2 minutes to record a single ‘frame’ 100x150 pixel blood flow image. The effect of possible temporal variations in tissue perfusion recorded with the moorFLPI are therefore greatly reduced.

The moorFLPI uses a diverging infrared laser beam and is classified as a Class 1 laser product (IEC 60825-1:2001). Class 1 laser products are generally regarded as non-hazardous to the eye and skin and protective eyewear is not required to be worn by the operator or patient. The predicate device uses a collimated laser beam of the same wavelength and is classified as a Class 3R laser product (IEC60825-1:2001) and as such is potentially harmful to the eye. The lower laser classification of the moorFLPI provides an increased level of safety compared with the predicate device.

The moorFLPI and the moorLDI2-IR both measure tissue perfusion by making use of the Doppler frequency shifts that result from coherent laser light being scattered

from moving red blood cells. The moorFLPI measurement of blood perfusion depends on analysing the speckle pattern contrast that results from interference between the Doppler shifted laser light and the laser light scattered from the tissue in which the blood is moving, whereas the moorLDI2-IR measurement of blood perfusion depends on direct measurements of the Doppler frequency shifts. The speckle pattern contrast is generated mainly by laser light scattered from the superficial layers of tissue. Detected light coming from deeper regions e.g. from underlying veins, is of low intensity and contributes little to the recorded light intensity. Flow in veins that are more than a mm or so below the surface are not imaged by the moorFLPI; however because the moorLDI2-IR is measuring the Doppler frequency shifts and calculates blood flow from the first moment of the integrated power spectral density of the detected photocurrent, (i.e. the frequency weighted power spectral density), it records not only the blood flow in the superficial tissue layers but also the faster flow in underlying veins.

Both the moorFLPI and the moorLDI2-IR can be used to image flow in small blood vessels exposed during open surgery.

7.4 Performance Data

In order to evaluate the performance of the moorFLPI Full-Field Laser Perfusion Imager, and determine its substantial equivalence to the predicate device (moorLDI2-IR), a set of comparison tests has been carried out. These include measurements from a simple flow model and single point and image scans from blood flow in skin, using both devices. The results show that the moorFLPI, within its specified range for flow measurements and area of tissue that can be imaged, has substantially the same performance as the predicate device for measurements of superficial blood flow.

The moorFLPI Full-Field Laser Perfusion Imager has been designed and tested for compliance with the standards for electrical safety, laser radiation safety, electromagnetic compatibility and programmable medical device.

7.5 Conclusions

From the description of the technological characteristics and the performance data, it can be concluded that the moorFLPI Full-Field Laser Perfusion Imager is substantial equivalence to the predicate device moorLDI2-IR laser Doppler imager in terms of effectiveness and safety.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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JAN 25 2007

Re: K063586

Trade/Device Name: moorFLPI Full-Field Laser Perfusion Imager
Regulation Number: 21 CFR 870.2120
Regulation Name: Extravascular blood flow probe
Regulatory Class: II
Product Code: DPT, GEX
Dated: November 27, 2006
Received: December 1, 2006

Dear Xiabing Huang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

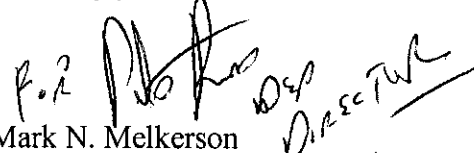
Page 2 – Xiabing Huang

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5 Indications for Use Statement

510(k) Number: K 063586

Device name: moorFLPI Full-Field Laser Perfusion Imager

Indications for use:

The moorFLPI Full-Field Laser Perfusion Imager is intended for blood flow measurements in the microcirculation. This device is intended for clinical research use.

Prescription Use: Yes
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use: No
(21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K 063586